

§ 1306.32 Dispensing without prescription.

A controlled substance listed in Schedule V, and a controlled substance listed in Schedule II, III, or IV which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

(a) Such dispensing is made only by a pharmacist (as defined in § 1306.02(d)), and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a nonpharmacist);

(b) Not more than 240 cc. (8 ounces) of any such controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other such controlled substance nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given 48-hour period;

(c) The purchaser is at least 18 years of age;

(d) The pharmacist requires every purchaser of a controlled substance under this section not known to him to furnish suitable identification (including proof of age where appropriate);

(e) A bound record book for dispensing of controlled substances under this section is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of § 1304.04 of this chapter); and

(f) A prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State or local law.

[36 FR 7799, Apr. 24, 1971, as amended at 36 FR 18733, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

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AUTHORITY: 21 U.S.C. 821, 822(d), 871(b), unless otherwise noted.

SOURCE: 36 FR 7801, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

GENERAL INFORMATION

§ 1307.01 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term *Act* means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(b) Any term not defined in this section shall have the definition set forth in section 102 and 1001 of the Act (21 U.S.C. 802 and 951) and in § 1301.02 of this chapter.

§ 1307.02 Application of State law and other Federal law.

Nothing in parts 1301–1308, 1311, 1312, or 1316 of this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted

to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he desires to do such act nor shall compliance with such parts be construed as compliance with other Federal or State laws unless expressly provided in such other laws.

§ 1307.03 Exceptions to regulations.

Any person may apply for an exception to the application of any provision of parts 1301-1313, or 1316 of this chapter by filing a written request stating the reasons for such exception. Requests shall be filed with the Administrator, Drug Enforcement Administration, Department of Justice, Washington, D.C. 20537. The Administrator may grant an exception in his discretion, but in no case shall he be required to grant an exception to any person which is not otherwise required by law or the regulations cited in this section.

[60 FR 32454, June 22, 1995]

SPECIAL EXCEPTIONS FOR MANUFACTURE AND DISTRIBUTION OF CONTROLLED SUBSTANCES

§ 1307.11 Distribution by dispenser to another practitioner.

(a) A practitioner who is registered to dispense a controlled substance may distribute (without being registered to distribute) a quantity of such substance to another practitioner for the purpose of general dispensing by the practitioner to his or its patients: Provided, That:

(1) The practitioner to whom the controlled substance is to be distributed is registered under the Act to dispense that controlled substance;

(2) The distribution is recorded by the distributing practitioner in accordance with § 1304.24(e) of this chapter and by the receiving practitioner in accordance with § 1304.24(c) of this chapter;

(3) If the substance is listed in Schedule I or II, an order form is used as required in part 1305 of this chapter;

(4) The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section and § 1301.28 of this chapter during each calendar year in which the practitioner is registered to dispense

does not exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the same calendar year.

(b) If, during any calendar year in which the practitioner is registered to dispense, the practitioner has reason to believe that the total number of dosage units of all controlled substances which will be distributed by him pursuant to this section and § 1301.28 of this chapter will exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed by him during that calendar year, the practitioner shall obtain a registration to distribute controlled substances.

[36 FR 18733, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 50 FR 31590, Aug. 5, 1985]

§ 1307.12 Manufacture and distribution of narcotic solutions and compounds by a pharmacist.

As an incident to a distribution under § 1307.11, a pharmacist may manufacture (without being registered to manufacture) an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in a proportion not exceeding 20 percent of the complete solution, compound, or mixture.

[36 FR 18733, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1307.13 Distribution to supplier.

Any person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he obtained it or to the manufacturer of the substance, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address, and registration number, if any, of the person making the distribution, and the name, address, and registration number, if known, of the supplier or manufacturer. In the case of returning a controlled substance listed in Schedule I or II, an order form shall be used in the manner prescribed in part 1305 of this chapter and be maintained as the written record of the